

Appl. No. 09/852,958

Amendment Dated June 15, 2004

Reply to Office Action of October 3, 2003

REMARKS/ARGUMENTS

In the Office Action dated October 3, 2003, claims 1-108 were subjected to restriction and/or election requirement. The Restriction Groups were set out as follows:

Group 1. Claims 1-17, 19-20, 27, 30, 33 are drawn to an inhibitor of in vitro cancer cell proliferation classified in Class 530, subclass 387.1.

Group 2. Claim 18 drawn to a method of making a steroid hormone reversible cancer cell growth inhibitor composition classified in Class 530, subclass 387.1.

Group 3. Claim 21 is drawn to a negative serum composition, classified in Class 530, subclass 387.1.

Group 4. Claims 22-23 are drawn to method of making a negative serum composition, classified in Class 530, subclass 387.1.

Group 5. Claims 24-26 are drawn to a control serum concentration, classified in Class 530, subclass 387.1.

Group 6. Claims 28-29 are drawn to a method of making a substantially steroid hormone-depleted serum, classified in Class 530, subclass 387.1.

Group 7. Claim 31 is drawn to a different method of making a substantially steroid hormone-depleted serum, classified in Class 530, subclass 387.1.

Group 9. Claim 32 is drawn to a method of making a purified immunoglobulin inhibitor, classified in Class 530, subclass 387.1.

Group 10. Claims 34-43 are drawn to an in vitro method for detecting steroid hormone-like cancer cell growth stimulation, classified in Class 435, subclass 4.

Group 11. Claim 44 is drawn to a method of determining a steroid hormone antagonistic substance, classified in Class 435, subclass 4.

Group 12. Claims 45-55 are drawn to a culture medium classified in Class 435, subclass 253.6.

Group 13. Claim 56 is drawn to an in vitro method of culturing cancer cells, classified in Class 435, subclass 253.6.

Group 14. Claim 57 is drawn to an in vitro method of detecting a cell growth stimulatory effect classified in Class 435, subclass 4.

Group 15. Claims 57-58 are drawn to an in vitro method of detecting a cell growth inhibitory effect classified in Class 435, subclass 4.

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Group 16. Claims 59-61 are drawn to a method of producing a biomolecule classified in Class 435, subclass 252.3.

Group 17. Claims 63-69 are drawn to an assay kit classified in Class 435, subclass 810.

Group 18. Claims 70-72 are drawn to a method of measuring the amount of steroid hormone reversible inhibitor in a sample of body fluid, classified in Class 435, subclass 4.

Group 19. Claims 73-74 are drawn to a an in vitro method of detecting an immunoglobulin inhibitor in a sample, classified in Class 435, subclass 4.

Group 20. Claims 75-86 are drawn to an in vitro cell model classified in Class 435, subclasses 4, 325.

Group 21. Claims 87-92 are drawn to a cell line, classified in Class 435, subclass 325.

Group 22. Claim 93-94 is drawn to a mediator of estrogen responsiveness, the estrogen receptor gamma, Classified in Class 530, subclass 350+.

Group 23. Claims 95-98 are drawn to a method of detecting an estrogenic substance, classified in Class 435, subclass 4.

Group 24. Claims 99-101 are drawn to a method of detecting an anti-estrogenic substance, classified in Class 435; subclass 4.

Group 25. Claims 102 is drawn to identifying an estrogen responsive cell, classified in Class 435, subclass 4.

Group 26. Claims 103-107 are drawn to a different method of inhibiting/killing cancer in vitro, classified in Class 514, subclass 2.

Group 27. Claim 108 is drawn to a method of measuring the concentration of steroid hormone, classified in Class 435, subclass, 4.

The Examiner pointed out a typographical error in claim 86, which has been corrected as indicated in the foregoing claim amendments.

Status of the Claims

Claims 1-4, 11, 87-94 and 102-108 have been canceled without prejudice to their being reintroduced in a continuing application.

Claims 5-10, 12-33, 59-61 and 63-72 stand withdrawn.

Claims 34, 38, 44, 56, 63, 86, 95 and 99 are currently amended.

New claims 109-122 have been added.

Claims 34-58, 62, 73-86, 95-101 and 109-122 are pending.

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Election with Traverse

Applicant elects with traverse to prosecute the claims of Group 10. It is submitted that the assays, testing methods and *in vitro* cell culture models of at least Groups 11, 13, 14, 15, 19, 20, 23 and 24 have sufficient similarity and interrelationship to those of Group 10 that it would be reasonable and not unduly burdensome to search the claims together. As evidence, the claims of each of Groups 10, 11, 14, 15, 19, 20, 23 and 24 are classified in Class 435/Subclass 4.

It should be noted that claim 45 is a linking claim which links the claims of Group 12 with the claims (as originally presented) of each of Groups 13, 14 and 15. More particularly, original claim 56 (Group 13), original claim 57 (Group 14) and original claim 58 (Group 15) each recite dependency from claim 45 (Group 12). It can also be readily appreciated that the method recited in claim 56 (Group 13) shares steps, techniques and materials with claim 34 (Group 10) and claim 44 (Group 11). For instance, carrying out the assay method of claim 34 or 44 requires culturing steroid hormone responsive cancer cells, as in claim 56. Likewise, the *in vitro* cell culture model (claim 75; Group 20) recites the same cell culture medium limitations as claim 45. Claim 73 of Group 19 is a variation on the assay of claim 34 which permits identification of an inhibitor instead of a steroid hormone-like substance. The underlying assay methods and materials are similar. Because of this close relationship, it is reasonable and not unduly burdensome to also search and examine Groups 10 and 19 together.

The cell culture medium of one or more of claims 45-55 (Group 12) are useful in the methods of Groups 10, 11, 13, 14, 15, 19, 20, 23 and 24, and, as noted above are expressly linked to the original claims of Groups 13-15. To make the interrelationships between other claims even more apparent, claims 34 and 44 are currently amended to link the recited "nutrient medium" to that of claim 45. New claims 109-114 have been added to depend from claim 34 and recite the limitations of claims 46, 47, 49, 51, 54 and 55. Similarly, new claims 115-122 have been added to depend from claim 44 and include the limitations of claims 46, 47, 49 and 51-55. Claims 95 and 99 are also currently amended to depend from claims 34 and 44, respectively. Thus, it would be appropriate to combine Groups 10 and 23, and it would be appropriate to combine Groups 11 and 24.

It can also be readily appreciated that the assay kits of claims 63-69 (Group 17) are uniquely applicable to carrying out the methods of Group 10. To make this relationship clearer, claim 63 is currently amended to require the culture medium of claim 45.

For at least the foregoing reasons, and in view of the linked nature of certain claims, Applicant believes that it is reasonable and not unduly burdensome for the Office to search and

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examine at least the linked claims from Group 12 together with the claims of combined Groups 10, 11, 13, 14, 15, 17, 19, 20, 23 and 24.

Claim 56 is further amended herein to include culturing of thyroid hormone responsive cells as well as steroid hormone responsive cells. The amendment also provides for reversal of inhibition of thyroid hormone responsive cell growth by thyroid hormone. This aspect of claim 56 is supported in Figure 134 and in the specification in Examples 5 and 21G, and paragraphs 230 and 311, for example. "[T]he 34°C CDE method described in the preceding Examples is clearly functional to demonstrate both steroid hormone and thyroid hormone growth effects in culture. It is known that the thyroid hormone receptor is a member of a superfamily of receptors that also includes the steroid hormone receptors... "

Please note that in the Office Action of October 3, 2003, there is no Group 8, and claim 62 has not been assigned to any restriction group. It also appears that claims 88-92 (relating to estrogen receptor gamma) should be included with Group 22 instead of Group 21. It is also submitted that Group 13 (claim 56) is better classified in Class 435, subclass 4 or 325, instead of the present classification (435/253.6), which pertains to media for bacteria.

Applicant respectfully requests that the restriction requirement be redrawn in light of the foregoing amendments and remarks, and that at least the following claims be examined together in this application:

Group 10. Claims 34-43 and new claims 109-115 (*in vitro* method for detecting steroid-hormone-like cancer cell growth stimulation).

Group 11. Claim 44 and new claims 116-122 (*in vitro* method of determining a steroid hormone antagonist).

Group 12. Claims 45-44 (cell culture medium).

Group 13. Claim 56 (*in vitro* method of culturing cancer cells).

Group 14. Claim 57 (*in vitro* method of detecting cell growth stimulatory effect).

Group 15. Claim 58 (*in vitro* method of detecting cell growth inhibitory effect).

Group 17. Claims 63-39 (assay kits)

Group 19. Claims 73 and 74 (*in vitro* method of detecting an immunoglobulin inhibitor).

Group 23. Claims 95-98 (*in vitro* method of detecting an estrogenic substance).

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Group 24. Claims 99-101 (*in vitro* method of detecting an anti-estrogenic substance).

The undersigned respectfully requests a telephonic Examiner Interview to facilitate the resolution of any unresolved issues pertaining to restriction groups and election. Should any fees have been inadvertently omitted, or if any additional fees are required or have been overpaid, please appropriately charge or credit those fees to Deposit Account Number 03-2769 of Conley Rose, P.C., Houston, Texas, and consider this a petition for any necessary extension of time.

Respectfully submitted,



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AGENT FOR APPLICANTS